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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/904,248	07/11/2001	Zhi Hong	330.074-US1	2104

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EXAMINER

WESSENDORF, TERESA D

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 11/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/904,248

Applicant(s)

HONG ET AL.

Examiner

T. D. Wessendorf

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/30/03 has been entered.

Status of Claims

Claims 1-20 have been canceled in the Amendment of 12/6/02.

Claims 21-26 are under consideration.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 21, as amended, is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written

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description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The as-filed specification fails to provide a description for the new claim "mononucleosides." The as-filed disclosure and the claims recite nucleosides i.e., more than one mer e.g., a chemically distinct polymer sequences. This is evident from the claim which recites that each of the first and second distinct mononucleosides contain each two reactive groups presupposing more than one mononucleoside for the first mononucleoside. That is, sequences or series of mononucleoside for the first and second mononucleoside to form each an individual nucleoside library. MPEP 714.02 states that applicants should clearly point out where in the specification support for the newly added limitation can be found.

Claims 21-26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for cytidine and adenosine, does not reasonably provide enablement for any type of heterocyclic or sugar containing mononucleosides. The specification does not enable any person skilled in the art to which it pertains, or with which it is

most nearly connected, to make and use the invention commensurate in scope with these claims.

The scope of enabling disclosure provided in the specification is not commensurate in scope with the broad claimed invention. The broad claimed synthesis employ any type of heterocyclic base and sugar that can be modified either in the heterocyclic or sugar moiety under any type of conditions or reagents. However, as evident from the prior art teachings e.g., Rodenko (J. Chem.Soc. Perkin Trans.) appropriate synthesis of nucleosides can be achieved using only the appropriate reagents under appropriate conditions. Determining these numerous variables for any type of heterocyclic-sugar complex would require undue experimentation to determine. This is the more true since the claims do not recite any structure for the heterocyclic base covalently coupled to any sugar moiety.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21-26, as amended, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to

particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As a preliminary matter, the rejection of the claims in the previous Office action has been overcome with the amendments to the claims. However, the newly presented claims are rejected as follows:

1. The description of the method of generating a library in the claimed terms provide for confusion and ambiguity as to whether in fact the desired product is obtained. There is no differentiating characteristic in structural sense of the relative terms "first", "second", "third" and "fourth" mononucleosides or the definitive product resulting therefrom. [It is suggested that applicant claim the method steps in terms of the reactions of the structure as shown in the specification, e.g., page 8]. Claim 21 is confusing as the preamble recites a mononucleoside library. The body recites a modified mononucleoside library. Furthermore, a reagent is normally used to initiate reaction between two products rather than a modifying agent. [It is suggested that applicants point out where specifically in the specification the use of a reagent results in a reagent attached to the mononucleoside to result in a modified mononucleoside].

2. Claim 23 used of the phrase "is disposed" is unclear as to the step covered by said phrase.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Polouchine (U.S. 5,902,879).

Polouchine discloses e.g., at col. 14, Examples a method of producing a modified Nucleosides Combinatorial Libraries comprising the steps wherein the amino group of 5'-methoxytrityl-2'-deoxy-2'-amino-nucleosides 1 can be selectively methoxyoxalylated with in situ prepared methyl oxalyl tetrazolide or, more preferably, with methyl oxalate, to form 2'-methoxyoxalamido precursor. Upon treatment with a proper nucleophile, such as an aliphatic primary or secondary amine (particularly an amino attached to an aliphatic carbon), ammonia or hydroxy anion, precursor 2 forms a corresponding 2'-modified

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nucleoside 3. Upon treatment with a mixture of different nucleophiles, the combinatorial library of 2'-modified nucleosides may be produced. Accordingly, the method of Polouchine, which recites specific method steps using specific reagents under specific conditions fully, meets the broad claimed method.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

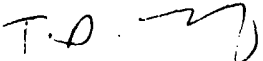
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7924 for regular communications and (703) 308-7924 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


T. D. Wessendorf
Primary Examiner
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tdw

November 25, 2003